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Health Law Pulse

January 2017

OIG Issues Favorable Advisory Opinion for Cost-Sharing Waiver and Stipend Arrangements in a Government-Funded Clinical Research Study

The Office of Inspector General (OIG) recently issued a favorable advisory opinion (Advisory Opinion) to a university health system (Requestor) regarding two arrangements: (1) a proposal to waive cost-sharing obligations of individuals for medically necessary health care services received as part of a federally funded clinical research study (Study) (Proposed Arrangement) and (2) the payment of a stipend to study participants for the time and effort required to participate in the Study (Current Arrangement) (collectively, Arrangements). The OIG concluded that, while the Arrangements have the potential to generate prohibited remuneration under the anti-kickback statute (AKS), the OIG would not impose administrative sanctions or civil monetary penalties (CMPs) on the Requestor because the Arrangements present only a minimal risk of fraud and abuse.

THE ARRANGEMENTS

The Study is a strategy trial that aims to determine whether treating anal high-grade squamous intraepithelial lesions (HSIL) is effective in reducing the prevalence of anal cancer in HIV-infected individuals. It was developed by a physician-employee of the Requestor and is funded exclusively through a Public Health Service grant awarded by the National Cancer Institute (NCI) to the AIDS Malignancy Consortium (AMC). No commercial enterprise provided input or support to the Study. Individuals were eligible to participate in the Study if they were HIV infected and screened as positive for anal HSIL. Participants are tracked for a period of time, and the Requestor stated that, for the successful completion of the Study, it is essential that participants remain compliant with the schedule of visits and services required by the Study protocol.

Generally, Study participants are responsible for the out-of-pocket cost-sharing for the routine costs of medically necessary items and services administered in connection with research studies where third-party payors (including government payors) continue to be billed for these items and services. Under the Proposed Arrangement, with prior approval from NCI, NCI funds will be used to reimburse Study participants for these cost-sharing obligations for Study-related, medically necessary health care services. The Study trial sites will waive participants' cost-sharing amounts, request reimbursement from the Requestor, and continue to bill and collect from third-party payors (including federal health care programs). According to the Requestor, the Proposed Arrangement will promote Study accessibility for participants and will also ensure compliance with treatment, thus promoting accuracy in the Study's results.

In addition to expenses for medically necessary care, Study participants also incur expenses they would not incur if they were not participating in the Study. The Study requires a substantial time commitment from participants, and the Study-related health care services could result in significant out-of-pocket expenses for participants, including travel and time off from work. Under the Current Arrangement, Study participants are reimbursed through a stipend system for their time commitment and expenses incurred that are related to every Study visit. The stipend applies even if visits involve both Study-scheduled clinical care billed to third-party payors and nonbillable, research-only activities. Stipend amounts vary between $100 and $25 per visit, depending on the procedures performed during Study visits. These amounts were determined by Study management through the detailed consideration of various Study factors, such as participant inconvenience, potential lost wages, expenses incurred, the need to encourage participation, and the nature of the Study procedures. According to the Requestor, NCI has also approved the expenditure of grant funds for the Current Arrangement.

OIG FINDINGS

The AKS makes it a crime to knowingly and willfully offer or receive remuneration to induce or reward referrals of items or services reimbursable by a federal health care program. The OIG found that the Proposed Arrangement implicated the AKS and the CMP because the cost-sharing waivers were intended to encourage eligible individuals to enroll and participate and because the Study sites will continue to bill and collect reimbursement from third-party payors (including federal health care programs) in connection with the Study. The OIG also found that the Current Arrangements implicated the AKS and the CMP because remuneration in the form of stipends is provided to federal health care program beneficiaries to enroll in, and remain compliant with, health care services provided as part of the Study.

Although both Arrangements would implicate the AKS and CMP, the OIG determined that the Arrangements present a low risk of fraud and abuse. Specifically, the OIG stated that the following features of the Arrangements certified by the Requestor minimize the risk of prohibited remuneration: (1) the Study is conducted as an AMC protocol and is financed exclusively through the Public Health Service grant awarded by NCI, which approved the expenditure of grant funds for the Arrangements and appointed an independent monitor to perform certain monitoring and reporting duties; therefore, the Arrangements are consistent with NCI policy objectives and subject to government oversight; (2) the Study aims to enroll a widely diverse group of participants, and compliance with the schedule of Study visits and services is essential to the successful completion of the Study; therefore, the Arrangements appropriately address hurdles to these objectives (that is, the protocol requires services that may be uncomfortable and time-consuming, the Study is a cancer prevention study rather than a cancer treatment study where participants would have felt an urgent need to comply with the treatment plan, and the cost-sharing obligations could be a substantial financial burden to Study participants); and (3) the Study is a strategy trial and not intended to develop, study, or benefit any specific commercial product or entity. Furthermore, the physically uncomfortable and time-consuming nature of the services offered by the Study make it improbable that Study participants will self-refer to the Study for unnecessary services.

CONCLUSION

While the Arrangements implicate the AKS and the CMP, the OIG found that the above-listed factors result in the Arrangements presenting a minimal risk of fraud and abuse. Thus, the OIG would not impose sanctions on the Requestor in connection with the Arrangements. Research sites and investigators contemplating an arrangement that involves the waiver of cost-sharing obligations for study participants in government-funded studies may wish to carefully consider the OIG's interpretation of the AKS and the CMP in the Advisory Opinion, bearing in mind that the Advisory Opinion is limited to the specific facts of the Arrangements.

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